REMARKS

Claims 1-20 and 35-37 are currently pending in this application, as amended. A Request for Continued Examination (RCE) under 37 C.F.R. § 1.114 is filed herewith. Claims 21-34 were previously canceled for being directed to a non-elected invention. Claims 1 and 12 have been amended to more particularly point out and distinctly claim the invention. Support for the claim amendments can be found in, among other places, the originally submitted Specification at paragraphs [0044], [0046]-[0050]; paragraphs [0054]-[0056]; and Figs. 1, 3, 7 and 9. Accordingly, no new matter has been added.

Claim Rejections Under 35 U.S.C. § 103(a)

Rejection of Claims 1 and 4-9

Claims 1 and 4-9 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,398,678 ("Gamow") in view of U.S. Patent No. 2,998,009 ("Holm *et al.*," hereinafter, "Holm"), U.S. Patent No. 1,224,180 ("Lake") and U.S. Patent No. 3,006,339 ("Smith").

Withdrawal of the rejections of claims 1 and 4-9, as amended, is respectfully requested in view of the foregoing amendments and for at least the following reasons.

Gamow

Gamow discloses a portable hyperbaric enclosure ("mountain bubble") with a means for maintaining a gas pressure of 10 pounds per square inch (PSI) including a blower and a gas (oxygen) tank. The portable hyperbaric enclosure is used in conjunction with an oxygen source delivered by a pressure regulator and with a carbon dioxide scrubber so as to maintain a pressurized environment with an appropriate level of breathable oxygen for a person inside the enclosure.

Holm

Holm discloses an electro-mechanically regulated apparatus (i.e., response element to magnet to induced signal to valve), primarily for air that is being continually re-

breathed, that "automatically maintains oxygen content" of the air (breathable gas) such as for deep-sea diving. The device conducts a current of gas that has been breathed by a human being past a sensor that is "responsive" to a percentage of oxygen in the medium in order to prevent either an oversupply or an under supply of oxygen. The sensor includes a rotatable or swingable body that is influenced to rotate by the paramagnetic properties of different concentrations of nitrogen and oxygen in a standard gas versus a sample gas. When the rotatable body moves between pole pieces of a fixed magnet, an electrical current is induced which is then amplified and used to control a normally open oxygen control valve. (see col. 3, lines 20-72).

Lake

Lake discloses an electro-mechanically (i.e., thermostatically) regulated apparatus for controlling gas temperature in a compression/vacuum chamber designed for humans. Lake discloses a thermostat that controls a solenoid which directs or diverts a flow of air through a heat exchanger to directly control the temperature of the air in a chamber. Lake also has an air regulator for controlling pressure and a source of purified air. While a thermostat electromechanically responds to temperature by opening and closing bi-metallic contacts, the thermostat does not output an electrical signal representative of a temperature sensed (i.e., the thermostat merely opens or closes at a particular setpoint) and does not display an indication of temperature or of a setpoint.

Smith

Smith discloses an electrical oxygen control system for a canopy 1 including a thermal conductivity analyzer 43 and a meter relay 61. The balance point of the analyzer 43 is determined by adjusting a potentiometer 58 until a needle 62 in the meter relay 61 is zeroed. A needle adjustment screw S is then used to move the needle to 21% (i.e., assuming that the room oxygen concentration is typical of air). Pure oxygen is then fed across a thermal conductivity cell 32 and the needle 62 should read in excess of 95% [oxygen]; otherwise, a potentiometer/rheostat 65' is used to set the full scale meter deflection to correspond to pure oxygen. Col. 3, lines 35-63. Meter contacts 63, 64 are then set by a knob *n* to set the control range of the oxygen content in the canopy 1. In operation, the thermal conductivity analyzer 43 causes the primary needle 62 to move back and forth based upon the relative oxygen

concentration detected. When the oxygen concentration drops, the output of the thermal conductivity analyzer 43 drops which causes the needle 62 to engage contact 64 thereby operating a relay coil 67 which energizes solenoid 73 opening a low-limit valve 34 in order to supply a high flow of oxygen into a chamber 15. When the oxygen concentration increases, needle 62 will move away from the contact 64 closing the valve 34 so that oxygen will be supplied by a normally open valve 28. When the oxygen in the chamber 15 reaches a high limit, the needle 62 moves into engagement with a relay contact 63 thereby energizing a relay coil 66 which energizes a solenoid 72 to close normally the open valve 28.

Smith also mentions, but does not describe in detail, that the air-conditioning is controlled by a conventional thermostat 75. Col. 3, lines 35-41. Smith merely shows a circle with a line in Fig. 2 labeled as element 75.

Claim 1

Claim 1, as amended, recites, *inter alia*:

> a pressure vessel containing a gas, the vessel being capable of accommodating a patient;
> an oxygen breathing line at least partially within the pressure vessel, the oxygen breathing line delivering a supply of substantially pure oxygen to the patient within the pressure vessel;
> an oxygen concentration measurement apparatus for monitoring a concentration of oxygen in the gas, the oxygen concentration measurement apparatus including an oxygen analyzer coupled to one of an electronic and an electro-chemical oxygen concentration sensing unit that provides an electrical output signal representative of the concentration of oxygen in the gas to the oxygen analyzer, the oxygen analyzer displaying an indication of oxygen concentration based on the electrical output signal, the oxygen analyzer including a user adjustable high alarm threshold and one of an audible and visual alarm, the respective one of the audible and visual alarm being activated when the concentration of oxygen in the gas is greater than or equal to the high alarm threshold....
> [underline emphasis added]

Gamow, Holm, Lake and Smith, taken alone or in combination, fail to disclose or suggest a hyperbaric oxygen therapy system having an oxygen breathing line at least partially

within the pressure vessel that delivers a supply of substantially pure oxygen to a patient within the pressure vessel and an oxygen analyzer including a user adjustable high alarm threshold and one of an audible and visual alarm, wherein the respective one of the audible and visual alarm is activated when the concentration of oxygen in the gas is greater than or equal to the high alarm threshold, as called for in amended claim 1.

In the present application, the breathable gas is nearly 100% pure oxygen delivered to a patient through a hood tent device or an oral/nasal mask 16 within the overall hyperbaric chamber 12 and exhausted directly outside the chamber 12 from that same hood or mask 16 without ever entering the "atmosphere" of the chamber 12 itself. In other words the Examiner is comparing claim 1 to patents that do not have a totally separate breathing system within a chamber pressurization system. The oxygen concentration being measured for alarming purposes is the "atmosphere" of the chamber 12, not the patient atmosphere delivered via the hood or mask 16. The larger chamber atmosphere is being monitored to prevent getting above the fire limit, e.g., high alarm limit of 22.5% oxygen, instead of the concentration of oxygen that the patient breathes, e.g., nearly 100% oxygen.

Gamow merely discloses a portable hyperbaric enclosure ("mountain bubble") with a means for maintaining a gas pressure of 10 PSI including a blower and a gas (oxygen) tank, used in conjunction with a pressure regulator and a carbon dioxide scrubber.

Holm merely discloses an electro-mechanically regulated apparatus (i.e., response element to magnet to induced signal to valve), primarily for air that is being continually re-breathed, that "automatically maintains oxygen content" of the air (breathable gas). While the sensor of Holm operates off of paramagnetic properties of the sensed gas, the system uses mechanical rotation or swinging of a body to move between poles pieces of a fixed magnet which creates an electric signal coupled directly to a control valve. Thus, Holm fails to disclose or suggest en oxygen analyzer including a user adjustable high alarm threshold and one of an audible and visual alarm, wherein the respective one of the audible and visual alarm is activated when the concentration of oxygen in the gas is greater than or equal to the high alarm threshold.

Lake fails to compensate for the deficiencies of Gamow and Holm. Lake discloses an electro-mechanically (i.e., thermostatically) regulated apparatus for controlling gas

temperature in a compression/vacuum chamber designed for humans. Lake has an air regulator for controlling pressure and a source of purified air, but lacks an oxygen concentration analyzer and any type of user adjustable alarm threshold and/or audible or visual alarm.

Smith fails to compensate for the deficiencies of Gamow, Holm and Lake. Smith discloses a thermal conductivity analyzer that drives a meter relay. The meter relay has two electromechanical relays which cause oxygen flow control valves to open and close as the measured oxygen value decreases and increases, respectively. Smith fails to disclose or suggest any sort of user adjustable alarm threshold and/or an audible or visual alarm.

The modified Gamow device discloses a chamber having the oxygen concentration of its internal atmosphere controlled by an electric oxygen monitor/controller.

To establish *prima facie* obviousness of a claimed invention, all of the claimed limitations must be taught or suggested by the prior art. MPEP § 2143.03. Thus, all of the claimed elements and features of claim 1 are not disclosed by the modified Gamow device.

The modified Gamow system would still not include hyperbaric oxygen therapy system having an oxygen breathing line at least partially within the pressure vessel that delivers a supply of substantially pure oxygen to a patient within the pressure vessel and an oxygen analyzer including a user adjustable high alarm threshold and one of an audible and visual alarm, wherein the respective one of the audible and visual alarm is activated when the concentration of oxygen in the gas is greater than or equal to the high alarm threshold, as recited in amended claim 1.

Applicants therefore respectfully submit that claim 1 is not obvious under 35 U.S.C. § 103(a) in view of the combination of Gamow, Holm, Lake and Smith. Claims 4-9 are dependent upon independent claim 1 and are therefore not obvious under 35 U.S.C. § 103(a) in view of the combination of Gamow, Holm and Lake for the same reasons mentioned with respect to claim 1 and because they each recite additional patentable elements and/or features. Accordingly, Applicants respectfully request that the rejection of independent claim 1 and dependent claims 4-9 under 35 U.S.C. § 103(a) be withdrawn.

Rejection of Claims 12-15

Claims 12-15 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Gamow in view of Lake and Smith.

Withdrawal of the rejections of claims 12-15 is respectfully requested in view of the foregoing amendments and for at least the following reasons.

Claim 12

Claim 12, as amended, recites, *inter alia*:

> a digital temperature controller having an adjustable set point which receives the electrical output signal of the temperature sensor and provides a control signal to the heat pump for adjusting the temperature of the exchange fluid to thereby maintain the temperature of the gas within a predetermined range of the set point, the digital temperature controller being configured to display a representation of the temperature sensed by the temperature sensor and the adjustable set point, the digital temperature controller having a control algorithm that controls the control signal, the control algorithm being based on at least one of time proportioning control, error proportioning control, proportional control, integral control and derivative control.
> [underline emphasis added]

Gamow, Lake and Smith, taken alone or in combination, fail to disclose or suggest a hyperbaric oxygen therapy system having a digital temperature controller having a control algorithm that controls a control signal, wherein the control algorithm [is] based on at least one of time proportioning control, error proportioning control, proportional (P) control, integral (I) control and derivative (D) control.

Gamow discloses a portable hyperbaric enclosure with a means for maintaining a gas pressure of 10 PSI including a blower and a gas (oxygen) tank. But, Gamow lacks any means of environmental temperature control. Lake discloses a thermostat that controls a solenoid which directs or diverts a flow of air through a heat exchanger to directly control the temperature of the air in a chamber. Smith also mentions, but does not describe, that the air-

conditioning is controlled by a conventional thermostat 75. Col. 3, lines 35-41. Smith merely shows a circle with a line in Fig. 2 labeled as element 75.

A thermostat electromechanically responds to temperature by opening and closing bi-metallic contacts. A thermostat is not a digital controller having a control algorithm such as time proportioning, error proportioning or P-I-D control.

Thus, all the claimed elements and features of claim 12, as amended, are not disclosed by the modified Gamow device. Applicants therefore respectfully submit that claim 12 is not obvious under 35 U.S.C. § 103(a) in view of the combination of Gamow, Lake and Smith. Claims 13-15 are dependent upon independent claim 12 and are therefore not obvious under 35 U.S.C. § 103(a) in view of the combination of Gamow, Lake and smith for the same reasons mentioned with respect to claim 12 and because they each recite additional patentable elements and/or features. Accordingly, Applicants respectfully request that the rejection of independent claim 12 and dependent claims 13-15 under 35 U.S.C. § 103(a) be withdrawn.

Allowable Subject Matter

The Examiner has stated that claims 2-3, 10-11, 16-20 and 35-37 are allowed.

CONCLUSION

It is respectfully submitted that the present application, including claims 1-20 and 35-37, is in condition for allowance, and such action is respectfully requested.

Respectfully submitted,

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